

Docket No. JANS-0008
JAB1461

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: McGee, et. al.

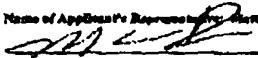
Serial No.: 09/868,991

Filed: July 26, 2001

For: Controlled-Release Galantamine
Composition

Examiner: Pulliam, A. E.

Art Unit: 1615

CERTIFICATE OF FACSIMILEI hereby certify that this correspondence is being facsimile
transmitted to the Patent and Trademark Office, Post No.
703-303-3392 on October 28, 2003.Name of Applicant's Representative: Matthew B. Zink

45257
Reg. No.The Commissioner For Patents
Alexandria, VA 22313-1450

Amendment and Response

Dear Sir:

INTRODUCTORY COMMENTS

In response to the Office Communication mailed August 19, 2003 and in view of the interview with the Examiner on October 16, 2003, please consider the following amendments and remarks. Filed herewith is a Request for Continuing Examination under 35 U.S.C. § 132

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As Dr. Truyen's declaration shows, on the basis of several clinical trials, Applicants surprisingly have discovered that use of the instantly claimed galantamine controlled-release ("CR") formulation results in an unexpected reduction in nausea and vomiting as compared to the commercially available immediate-release ("IR") galantamine formulation, and that, in the aggregate, this reduction is not tied to a reduction in the maximum blood plasma concentration as would be expected, but instead, is tied to the rate of rise of blood plasma concentration. Truyen Decl. ¶¶ 6, 13, 14. As noted in the interview, it is the water-insoluble polymer with optional plasticizer that largely determines the rate of rise of blood plasma concentration of galantamine in the presently-claimed invention, and claim 10 reciting this polymer and optional plasticizer is now the broadest independent claim. These unexpected results rebut any *prima facie* case of obviousness, as nausea and dizziness are significant side effects for galantamine. Truyen Decl. ¶ 9. Applicants therefore respectfully request that the Examiner withdraw the outstanding rejections under 35 U.S.C. 103(a).

Conclusion

For all of the reasons above, claims 2 - 29 are believed to be in condition for allowance, early notice of which would be appreciated. The Examiner stated that if she does not agree that all claims are allowable, then she would telephone Applicants' representative to discuss any remaining issues; Applicants gratefully acknowledge this courteous offer.

No fee is believed to be due with this response other than the fee for the Request for Continuing Prosecution. Authorization is hereby given to charge all required fees to Johnson & Johnson Deposit Account No. 10-0750/JAB 1461/MBZ.

Respectfully submitted,

By: 

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